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Cost Containment Starting in the 1980s:

(1) Utilization Review
(2) Mandatory Second Opinions
(3) Homecare and Hospice Care
(4) DME Networks
(5) Nurse Hotlines
(6) Subrogation
(7) Coordination of Benefits

Cost Containment in the Last Decade:

(1) Disease Management
(2) Prescription Step Therapy
(3) Specialty Drugs (High Cost Injectables)

Disease Management

These are the key features of a program to take Utilization Review to a deeper level, in cooperation with the patient:

A Disease Management Program monitors specific health concerns, such as

(a) Diabetes
(b) Heart failure
(c) Coronary artery disease
(d) Chronic obstructive pulmonary disease
(e) Asthma

Or (f) All diagnoses reaching a certain dollar threshold.

Disease Management

The Disease Management vendor identifies patients through claims and prescription data feeds and the pre-certification processes for treatment and hospital admission. Participants covered by the program can also enroll themselves for intervention. Many Disease Management vendors expect referrals from a central Human Resources or Labor contract—this is often not possible for a benefit plan.

Disease Management vendors use claims data to identify patients for intervention using

(a) Predictive modeling (multivariate)

(b) Gap analysis

One measure of the quality of a Disease Management vendor is the sophistication of its screening process to identify participants for intervention.

Disease Management

They solicit patient involvement through Outreach Services.

(a) mailings

(b) phone calls

There are variations in the services provided under Disease Management.

(a) Negotiation of medical provider fees

(b) Reporting of “best practices” back to medical providers

(c) Promoting the use of particular medical providers, centers of excellence

(d) Data mining

(e) Data warehousing

(f) Care guides—kits, DVDs

Disease Management

The contracting process may involve hiring a consultant to bring different Disease Management vendors for interview. The features to look for in a contract are as follows:

(1) Clear delineation of the responsibilities of the vendor and the Plan. The Plan must provide medical and/or prescription data to the vendor in a specified format, cooperation in the communication process to participants, calculation and payment of fees.
(2) HIPAA protections. The data required is purely Protected Health Information.
(3) Indemnification and insurance clauses, including proprietary materials.

Disease Management

(4) A description of the claims data and sources for that data to be used in identification and stratification of participants.

(5) The type and cycle of outreach services, including the health coaching services.

(6) Performing metrics.

(7) Reporting to those responsible for the Plan, including analytics.

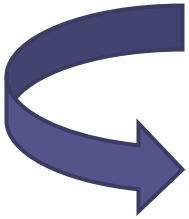
(8) An implementation and roll-out plan.

(9) Fees at risk—return on investment guarantee, including how savings are calculated.

(10) Termination clause.

(11) Audit rights.

Disease Management



Insights

(1) Most plans will want an ROI guarantee of at least 1:1. ROI notoriously difficult to prove.

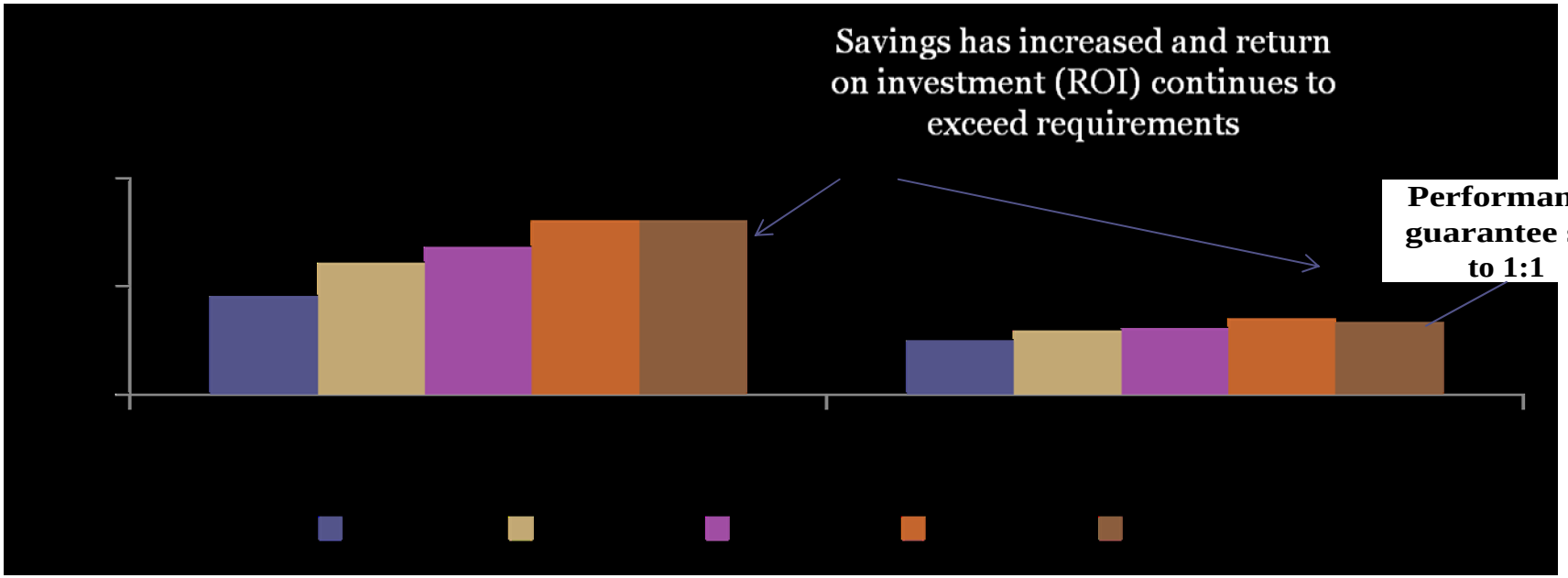
(2) The Plan will need to decide whether, once targeted for intervention, the participant must comply.

(3) Disease management programs are generally well-received by participant, but, ironically, poorly utilized.

Illustration of Disease Manager's Report

Program Year 5 Savings and ROI

Continued Success in returning value to the Fund



Measurement period defined as 9/1 – 8/31 for each program year (PY). PY5 data includes 4-months of claims run out.

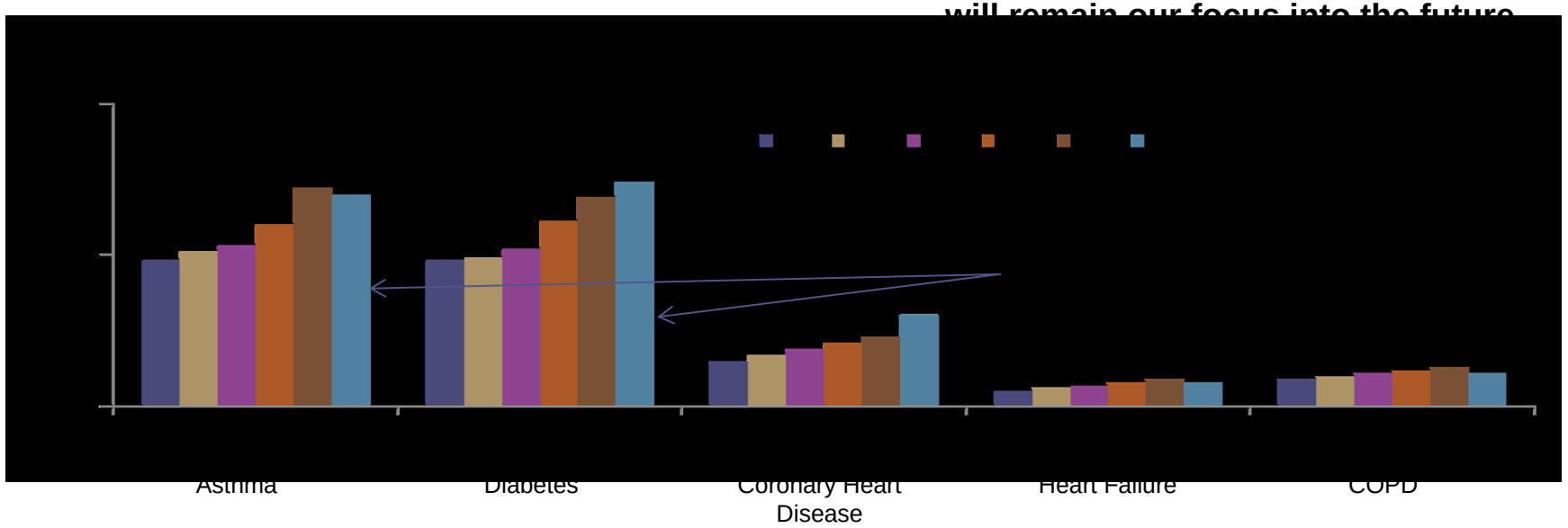
Illustration of Disease Manager's Report

Chronic Prevalence Trends

Continued focus on medical cost drivers

Population	Year 1	Year 2	Year 3	Year 4	Year 5
Non-Chronic	89.8%	89%	87.7%	85.4%	84.1%
Chronic	**10.2%**	**11.0%**	**12.3%**	**14.6%**	**15.9%**

Not unexpectedly, there has been a steady increase in chronic prevalence during the five program years. **Focusing the program on managing the cost and quality implication of this trend will remain our focus into the future.**



New England Journal of Medicine

A Randomized Trial of a Telephonic Case Management Strategy

- Stratified, randomized study of 174,120 individuals
- Compared impact on medical costs and utilization of two different care and decision support strategies in an insured population.
- Baseline costs and utilization identical in both groups
- Primary difference was that a larger proportion of intervention group was identified to receive outreach
- Primary outcome measures were total medical costs and hospital admissions after one year
- Bottom line:
  - Total costs **reduced by over 3.6%**
  - Total population **admissions reduced by 10.1%**
  - **Net savings of $6.00 pmpm**

Specialty Pharmacy

Specialty drugs are those with the following characteristics:

(1) Expensive – average $1,800 per treatment
(2) Complex handling, shipping, and storage requirements, causing the potential for waste
(3) Usually injectables, sometimes new to the market
(4) Most common diagnostic categories: cancer, cystic fibrosis, growth hormone deficiency, hemophilia, infertility, multiple sclerosis, rheumatoid arthritis

Specialty Pharmacy

When a physician administers an injectable in his/her office, the claim will contain an office visit code and a charge for the drug itself.

Often, doctors specializing in treatment of one of the above diagnoses will keep supplies of the injectables in a refrigerator in the office. The physician has paid for supplies of the drug and has an incentive to recoup the cost. Because the drugs are new to the market and may require compounding to precise units, there are generally no usual, customary, and reasonable (UCR) limits.

It is not uncommon for a specialty drug which costs $5,000 when administered from a doctor's supplies to cost far less—perhaps less than $1,000—when warehoused and shipped from a specialty vendor.

The drugs usually ship to the participant's home to be self-injected.

Specialty Pharmacy

A typical contract

(1) enumerates the specific services to be provided, including a list of the specialty drugs themselves, clinical support and education to be provided by the vendor concerning the drug, shipping, handling, and mailing logistics

(2) contains HIPAA protections

(3) describes the exchange of data required for the vendor to identify participants receiving specialty drugs (J code reporting)

Specialty Pharmacy

(4) establishes a procedure for written communications to those targeted for intervention

(5) sets forth the claims adjudication process

(6) lists the Plan's responsibilities

(7) describes the reporting to the Plan (interventions, drugs supplied, savings)

(8) includes performance guarantees and penalties

(9) includes indemnifications and limitation of liability clauses

(10) includes an exclusivity clause

(11) audit rights—new business devoted to auditing

Specialty Pharmacy

Insights

(1) Specialty drugs are covered under the medical plan if not targeted for specialty pharmacy. Once taken over by specialty pharmacy, the Plan must decide the co-payment to be taken by the PBM.

Prescription vendor contracting, even absent a Specialty Pharmacy program, is highly complex.

(2) Participants generally enjoy the convenience and potential savings (lower co-payment) of specialty drug programs.

Specialty Pharmacy

(3) The identification process is easier than it used to be—enhanced data transfer, including claims related to the most common diagnoses, may help the vendor locate eligible participants, as well as coordination with the utilization review manager providing hospital intake (such as for cancer).

(5) Sometimes specialty drugs are administered once or twice, and not again, making it impossible to intervene.

Step Therapy

Step therapy requires the use of a preferred drug, or for criteria to be met before a drug can be approved. If the criteria are not met, a prescription may reject at the pharmacy. Step therapy programs are implemented because certain drugs have less expensive alternatives, or because there are safety considerations on the prescribed drug.

Step Therapy

Historically, Step 1 medications were generics, Step 2 medications were brands.

Presently, many PBMs place select preferred brands on Step 1 along with the generics; this is a result of pharmacy manufacturers attempting to drive market share through point of service programs like Step Therapy vs. formulary placement as the sole driver of market share.

Insights:

- Prior to considering a Step Therapy program, Plan Sponsors should review the medications included in Step 1 to verify use of the lowest cost medication available to the member and the Plan—without consideration of rebates.

Step Therapy

- The PBM contract should address the PBM's obligation to limit drug switching programs, including via Step Therapies, to lower cost, therapeutically equivalent medications.

The table below illustrates a 2011 Step Therapy Program offered by a large PBM to their customers; note that Brand medications are in bold. The undiscounted average wholesale price (AWP) is included.

Step 1 Medications	AWP	Step 2 Medications	AWP
Crestor	$156.00	**Altroprev**	$280.00
Lipitor	$121.00	**Lescol**	$114.60
Lovastatin	$ 11.60	**Lescol XL**	$145.80
Pravastatin	$ 35.90	**Livalo**	$118.00
Simvastatin	$ 10.61	**Mevacor**	$ 86.10
		Pavachol	$128.70
		Vytorin	$139.00
		Zocor	$ 76.00

Step Therapy

Medications commonly requiring steps:

(1) Proton pump inhibitors for heartburn and acid reflux (Prilosec is inexpensive and now over the counter)
(2) COX-2 Inhibitors for arthritis and pain
(3) Singulair for asthma
(4) Mobic, an NSAID

The STEPS may require trial (14 days, 30 days) of one or more other drugs, or documentation of a particular risk, such as stomach bleeding.

Step Therapy

Sometimes drug programs have additional "clinical edits and restrictions" which are similar to step therapy, for example, quantity limits on oxycontin unless there is a diagnosis comporting with severity. Many Pharmacy Benefit Managers (PBMs) have become more sophisticated in their handling of the steps, requiring less manual effort on the part of the patient—for example, the computer system may be able to screen for the necessary diagnosis so that the drug automatically approves at the pharmacy level, rather than requiring the participant to obtain a manual authorization from the doctor. A higher level of computerization means less effort on the part of the patient.

Step therapy is usually an adjunct to an existing contract. Drugs are ultimately covered in the same way, with the same co-payments and restrictions.

Step Therapy

Insights

(1)The advent of generics has made step therapy less advantageous than it once was.

(2)Plan design has taken over. I.e. an equivalent for Lipitor for less cost.

(3)The Plan will need to decide what the penalty is should the steps not be followed, or whether an appeals process will allow leeway for a physician to recommend overriding the steps. If the steps are not followed, does the prescription remain uncovered by the Plan? Is the prescription filled the first time, with a warning that the next prescription will be subject to the steps?

(4)As with high-cost injectables, the Plan will need to decide whether to allow the PBM the ability to change the steps as new drugs enter the market, or as new studies or safety warnings occur—or whether to bring recommendations on a regular basis to the Plan.

(5)The Plan may want to talk to the vendor about helping with the cost of initial and ongoing communications about the program.